REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-8, 11 and 13 are pending in the application. Claims 9, 10, and 12-13 have been canceled.

In the outstanding Official Action, the election/restriction requirement was made final on the grounds that the NOVELLINO et al. publication was available as prior art. However, applicants submit herewith a verified translation of Italian application No. MI2002A002412, filed on November 14, 2002. As the NOVELLINO publication was filed after this date, applicants respectfully submit that the NOVELLINO publication fails to qualify as prior art. As the NOVELLINO publication fails to qualify as prior art, applicants respectfully submit that the Official Action fails to provide any evidence that any of the pending claims lack unity.

Accordingly, applicants respectfully request that the election/restriction requirement be withdrawn.

As noted above, applicants submit herewith a verified translation of Italian Application No. MI2002A002412, filed on November 14, 2002.

As to the objections to the specification, the specification has been amended as suggested by the Examiner. Applicants note

with appreciation the suggestions of the Examiner as how to overcome the prior art.

Claims 9-14 were objected to as allegedly being directed to non-elected subject matter. However, as noted above, applicants believe that the restriction requirement should be withdrawn. Indeed, it appears that claims 9-14 have already been substantively examined in the outstanding Official Action. Thus, applicants respectfully submit that the continued examination of claims 9, 11 and 13 does not place an undue burden on the Patent Office. Claims 10 and 12 have been canceled.

Claim 1 was rejected under 35 USC §101 for allegedly not satisfying statutory subject matter requirements. However, as suggested by the Examiner, claim 1 has been amended to recite an "isolated" immunogenic peptide. Applicants again thank the Examiner for the suggestion as how to overcome the rejection.

Claims 1 and 9-14 were rejected under 35 USC §112, second paragraph, for allegedly being indefinite.

The outstanding Official Action was objected to the term "the $PTPRK_{Gly677\rightarrow Arg682}$ immunogenic peptide of SEQ ID NO: 1". However, claim 1 has been amended to recite an isolated immunogenic peptide consisting of the amino acid sequence of SEQ ID NO: 1. Thus, applicants respectfully request that this rejection be withdrawn.

Claims 9-14 were rejected for reciting the phrase "peptide SEQ ID NO: 1". However, claims 9, 11 and 13 have been amended so that this phase is no longer recited.

Claims 12 and 14 were rejected for reciting "$PTPRK_{Gly677\rightarrow Arg682}$". As is recognized by the Examiner, the term "$PTPRK_{Gly677\rightarrow Arg682}$" is incorrect. Rather, the term should reflect "$PTPRK_{Gly677\rightarrow Arg}$". In this regard, the specification and claims have been amended to correct this informality. Indeed, it is clear from the present specification that the mutation of the PTPRK protein occurs at position 677, wherein a Gly residue is substituted with an Arg residue (see page 3, lines 13-15 and page 18, lines 5-10). Position 682 is not occupied by Arg. Rather, 682 indicates the terminal residue of peptide 667-682 and is not involved in the mutation itself. In this regard, applicants believe that the informality and the correction would have been both obvious to one skilled in the art.

Claims 1 and 9-14 were rejected under 35 USC §112, first paragraph, for allegedly not satisfying the written description rejection.

However, as noted above, independent claim 1 has been amended to recite an isolated immunogenic peptide consisting of the amino acid sequence of SEQ ID NO: 1. Accordingly, applicants believe that the changes to claim 1 obviate the written description rejection.

Claims 1 and 9-14 were rejected under 35 USC §112, first paragraph, as allegedly not satisfying the enablement requirement.

Applicants believe that the above-identified changes to claim 1 overcome a number of the issues related to the enablement rejection.

However, applicants wish to point out that immunogenic peptides are often used in producing vaccines, medicaments, and diagnostics.

For example, the Examiner's attention is respectfully directed to the following publications:

- Mocellin S, Rossi CR, Nitti D, Lise M, Marincola FM Dissecting tumor responsiveness to immunotherapy: the experience of peptide-based melanoma vaccines. Biochim Biophys Acta. 2003 Dec 5;1653(2):61-71. R

- Parmiani G, Castelli C, Dalerba P, Mortarini R, Rivoltini L, Marincola FM, Anichini A. Cancer immunotherapy with peptide-based vaccines: what have we achieved? Where are we going? J Natl Cancer Inst., 2002;94(11); 805-18.

- Weber J. Peptide vaccines for cancer. Cancer Invest. 2002;20(2):208-21.

- Beck A, Klinguer-Hamour C, Bussat MC, Champion T, Haeuw JF, Goetsch L, Wurch T, Sugawara M, Milon A, Van Dorsselaer A, Nguyen T, Corvala N. Peptides as tools and drugs for immunotherapies- J Pept Sci.2007(9):588-602.

- Pilla L, Valenti R, Marrari A, Patuzzo R, Santinami M, Parmiani G, Rivoltini L. Vaccination: role in metastatic melanoma. Expert Rev Anticancer Ther. 2006(8):1305-18.

- Talebi T, Weber JS. Peptide vaccine trials for melanoma: preclinical background and clinical results. Semin Cancer Biol. 2003(6):431-8.

• Brinkman JA, Fausch SC, Weber JS, Kast WM. Peptide-based vaccines for cancer immunotherapy- Expert Opin Biol Ther. 2004 (2):181-98,

• Sabel MS, Sondak VK. Tumor vaccines: a role in preventing recurrence in melanoma? Am J Clin Dermatol. 2002;3(9):609-16.

• Machiels JP, van Baren N, Marchand M. Peptide-based cancer vaccines. Semin Oncol. 2002(5):494-502.

Furthermore, page 22, lines 17-27 of the present specification describes the development of a systemic, epitope-specific T cell immunity induced by the claimed peptide. Peptide-specific T cells were found in the peripheral blood (Figure 7) and, proved able to recognize the autologous tumor.

Altogether these results indicate that the immunogenic peptide of the invention fulfill the requisites for clinical use, including the administration of diagnostic compositions, medicaments, and vaccines for stimulating the immune response against tumors, particularly against melanoma, as the claimed peptide represents the epitope of a mutated form of PTPRK ($PTPRK_{Gly677\rightarrow Arg}$) cloned from melanoma cells.

Nevertheless, in the interest of advancing prosecution, applicants note that claims 10, 12 and 14 have been canceled. Claims 9, 11 and 13 have been amended to broadly recite compositions. As the Examiner is aware, when a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991). However, when a compound or composition claim is not

limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for non-enablement based on how to use (see MPEP §2164.01(c).

Thus, in view of the changes to claims 9, 11 and 13, applicants believe that the claims plainly satisfy the enablement requirement. Claims 10, 12 and 14 have been canceled.

The Examiner is also respectfully reminded that it is a well founded principle that any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed.

As a matter of law, the expressed teaching of the patent specification cannot be controverted by mere speculation and unsupported assertions on the part of the Patent Office. As stated by the Court of Customs and Patent Appeals in the case of *In re Dinh-Nguyen and Stanhagen,* 181 USPQ 46 (CCPA 1974):

> Any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed. 181 USPQ at 47.

Such a standard must be applied with great care when the Examiner's conjecture is contrary to the teachings of the specification.

As the Official Action fails to provide any evidence that one skilled in the art would not be able to produce the claimed

immunogenic composition, diagnostic composition, or medicament, applicants respectfully submit that this is yet another reason for the Patent Office to withdraw the enablement rejection in its entirety.

Claims 1 and 9-14 were rejected under 35 USC §102(a) as allegedly being anticipated by NOVELLINO et al. This rejection is traversed.

As noted above, applicants submit herewith the verified translation of the Italian application No. MI2002A002412, filed November 14, 2002, so that the NOVELLINO publication does not qualify as prior art. In this regard, applicants respectfully request that the rejection be withdrawn.

In view of the present amendment and the foregoing remarks, therefore, applicants believe that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment

to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

- a verified translation of Italian Application No. MI2002A002412, filed on November 14, 2002